EXHIBIT B

No. 20-2330

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES EX REL. DEBORAH SHELDON,
Executrix of the Estate of Troy Sheldon,

Plaintiff-Appellant,

v.

ALLERGAN SALES, LLC,

Defendant-Appellee.

On Appeal from the United States District Court
for the District of Maryland

BRIEF FOR THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING APPELLANT

BRIAN M. BOYNTON
Acting Assistant Attorney General

MICHAEL S. RAAB
CHARLES W. SCARBOROUGH
JOSHUA DOS SANTOS
Attorneys, Appellate Staff
Civil Division, Room 7243
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 353-0213

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INTEREST OF THE UNITED STATES

The False Claims Act, 31 U.S.C. § 3729 *et seq.*, is the federal government's primary tool to recover losses from fraud in federal programs. The district court committed errors in this case that undermine important government interests in combating fraud and in ensuring that state Medicaid programs are able to obtain drugs at the best price that a drug manufacturer accepts in sales to private entities. The court held that a drug manufacturer's calculation of the "best price" for its drugs, which determines in part how much the manufacturer must pay in rebates to state Medicaid agencies, could not be "false" under the False Claims Act because the "best price" requirement was ambiguous. The court further held that such ambiguity precluded the relator from plausibly alleging that the drug manufacturer acted knowingly under the False Claims Act.

The district court's holdings would mean that, where liability is premised on the violation of a statutory or regulatory requirement, a defendant could defeat plausible allegations of both falsity and knowledge simply by identifying an ambiguity in the relevant requirement—even when the defendant had "actual knowledge" that it was violating the requirement or acted with "deliberate ignorance" or "reckless disregard" of the truth of its representations to the government. 31 U.S.C. § 3729(b)(1)(A)(i)-(iii). That holding fundamentally distorts and conflates falsity and knowledge under the False Claims Act.

STATEMENT OF THE ISSUES

1. Whether the district court erred in holding that some ambiguity in applicable reporting requirements prevented defendant's claims from being "false" as a matter of law, even though the court did not determine whether the relator's interpretation of those requirements was correct.

2. Whether the district court erred in holding, at the pleading stage, that the defendant's ability to identify a reasonable interpretation of applicable reporting requirements precluded the relator from plausibly alleging that defendant acted "knowingly" under the False Claims Act.

STATEMENT OF THE CASE

A. The False Claims Act

The False Claims Act imposes liability if a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). The statute also imposes liability if a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation … to the Government" or "knowingly conceals or knowingly and improperly avoids or decreases an obligation … to the Government." *Id.* § 3729(a)(1)(G).

In 1986, Congress defined the term "knowingly" as "actual knowledge of the information," "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information." 31 U.S.C.

§ 3729(b)(1)(A)(i)-(iii) (quotation marks omitted). The term "knowingly" "require[s] no proof of specific intent to defraud." *Id.* § 3729(b)(1)(B).

Either the Attorney General or a private person (known as a *qui tam* relator) may bring suits to collect statutory damages and penalties in the name of the United States. 31 U.S.C. § 3730(a), (b)(1); *see also Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769 (2000). If a relator files a *qui tam* action, the government may intervene and take over the case. 31 U.S.C. § 3730(b)(2). If the government declines to intervene, the relator conducts the litigation and divides the monetary proceeds with the government. *Id.* § 3730(c)(3), (d).

B. The Medicaid Drug Rebate Statute

The Medicaid program is a cooperative federal-state program that provides medical assistance to certain low-income individuals. *See* 42 U.S.C. § 1396 *et seq.*; *Harris v. McRae*, 448 U.S. 297, 301 (1980). To participate, states submit a plan to the Department of Health and Human Services' Centers for Medicare & Medicaid Services (CMS), and after approval states are eligible for federal reimbursement of a specified percentage of expenses under the state's plan. *See* 42 U.S.C. §§ 1396a, 1396b(a)(1), 1396d(b). Prescription drug coverage is one type of "medical assistance" that may be covered, *id.* § 1396d(a)(12), and every state provides such coverage in its Medicaid plan, *see* CMS, State Drug Utilization Data (last updated Jan. 4, 2021), https://go.usa.gov/xs6QS (listing every state as providing drug coverage).

In 1990, Congress discovered that Medicaid programs were routinely paying more for prescription drugs than private entities. *See* H.R. Rep. No. 101-881, at 96 (1990). To remedy that problem, Congress enacted the Medicaid Drug Rebate Statute, which "establish[ed] a rebate mechanism … to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *Id.*

Under this statute, drug manufacturers seeking to have their drugs covered by Medicaid must enter into Rebate Agreements with the Secretary of Health and Human Services, pursuant to which the manufacturer must pay each state a quarterly rebate per unit of drug paid under the state's Medicaid plan. *See* 42 U.S.C. § 1396r-8(a)(1), (c)(1)(A); *Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). For a unit of a single source drug or an innovator multiple source drug (essentially, brand-name drugs), the rebate amount is equal to the greater of two numbers: (1) the statutory minimum rebate percentage, or (2) the difference between the manufacturer's reported "best price" and the average price paid by wholesalers and retailers (called the "average manufacturer price"). 42 U.S.C. § 1396r-8(c)(1)(A). At the end of the rebate period, manufacturers must report their "average manufacturer price" and "best price" to CMS, which then calculates the unit rebate amount that the manufacturer must pay for each drug. *See id.* § 1396r-8(b)(3)(A).

The statute defines the drug manufacturer's "best price" as "the lowest price available from the manufacturer … to any wholesaler, retailer, nonprofit entity, or

governmental entity," which "shall be inclusive of cash discounts, … volume discounts, and rebates." 42 U.S.C. § 1396r-8(c)(1)(C)(i), (ii)(I). In 1991, CMS published a national Rebate Agreement implementing the statute, which the agency updated in 2018. *See* 56 Fed. Reg. 7049, 7050 (Feb. 21, 1991); 83 Fed. Reg. 12,770 (Mar. 23, 2018). The 1991 Rebate Agreement stated that "best prices shall be inclusive of cash discounts… and rebates," and that "[t]he best price for a quarter shall be adjusted by the Manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." 56 Fed. Reg. at 7050. A 1994 CMS Program Release explained that "best price" includes "any price adjustment which ultimately affects the price actually realized by the manufacturer." Medicaid Drug Rebate Program Release No. 14 at 1 (Dec. 21, 1994), https://go.usa.gov/xszGw (1994 Program Release).

In 2007, CMS also published a regulation stating that "Best price shall be calculated to include all sales and associated rebates, discounts and other price concessions provided by the manufacturer to any entity" and "shall be net of cash discounts … and any other discounts or price reductions and rebates … which reduce the price available from the manufacturer." 72 Fed. Reg. 39,142, 39,242-43 (July 17, 2007). It further provided that "[t]he manufacturer must adjust the best price for a

rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available from the manufacturer." *Id.* at 39,243.[1]

C. Prior Proceedings

Relator brought this declined *qui tam* action against defendant Forest Laboratories LLC (Forest), a drug manufacturer subsequently replaced in this litigation by Allergan Sales LLC. Relator alleges that Forest knowingly submitted inflated "best price" calculations that failed to reflect all of the rebates and discounts that Forest provided in the sale of its drugs, resulting in underpaid rebates to state Medicaid agencies by more than $680 million over several years. Joint Appendix (JA) 32, 39.

As recounted in the complaint, Forest often provided three types of discounts and rebates on the same drug units: (1) a chargeback discount to Pharmacy Providers and Group Purchasing Organizations (initially provided to those entities by a wholesaler, but the wholesaler "charged back" the discount to the manufacturer); (2) a rebate to the Pharmacy Providers and Group Purchasing Organizations based on the number of drug units purchased or dispensed; and (3) a rebate to insurers based on the number of drug units purchased and on the drug's listing on the insurer's formulary. JA32, 64-68.

[1] CMS subsequently modified the regulation's language in various ways. The current version is codified at 42 C.F.R. § 447.505(a).

Relator further alleges that Forest actually knew, or at least acted with deliberate ignorance or reckless disregard in not knowing, that its "best price" calculation had to include all of those discounts and rebates. JA34-35, 68-74. In particular, relator pointed to a letter that Forest sent asking CMS to clarify that "best price" did not include discounts offered to multiple entities. JA59-60. Relator also alleged that Forest adopted a data scrubbing system to identify duplicate rebates paid to secondary insurers, partly because Forest knew that paying rebates to two insurers for the same drug unit would alter the "best price." JA68-70.

The United States declined to intervene in this *qui tam* suit, and Forest moved to dismiss, arguing in part that "best price" did not include discounts provided to multiple entities.

The district court dismissed relator's claims, holding that relator failed to plausibly allege either falsity or knowledge under the False Claims Act. The court acknowledged at the start of its analysis that the question whether Forest made false statements "depends on the interpretation of the Rebate Statute." JA353. But the court did not answer the threshold legal question whether a manufacturer must aggregate discounts to multiple entities on the same drug unit when it reports its "best price" to CMS. Instead, the court held only that "the Rebate Statute may be susceptible to multiple interpretations." JA354, 360.

Based on that conclusion alone, the court rejected relator's allegation that Forest's "best price" reports were false. The court stated that relator's "allegations do

not suggest that defendant's interpretation is objectively unreasonable," and therefore "claims based on Forest's interpretation cannot qualify as objective falsehoods or constitute false statements under the [False Claims Act]." JA354-55, 360.

The court also held that, "because Forest's interpretation is objectively reasonable," "Relator cannot plausibly allege that Forest acted with the requisite scienter unless he can demonstrate that defendant had been warned about its interpretation." JA360-61. And although the court acknowledged that "some of the guidance could be read to support Relator's interpretation," it determined that "the guidance was not so clear as to warn Forest away from its interpretation." JA359-61.

SUMMARY OF ARGUMENT

I. Under the False Claims Act, a statement or claim is "false" if it is made in violation of applicable law or regulations. In such cases, courts assess falsity simply by determining whether the defendant violated applicable law. Here, the district court concluded that the relator failed to plausibly allege falsity, but did so without making the threshold legal determination whether defendant's alleged conduct violated the law. Instead, the court stated that the applicable law was ambiguous and ended its analysis there. That was error, and this Court should, at a minimum, reverse on this ground.

If the Court reaches the question, it should also conclude that relator plausibly alleged falsity. Under the Medicaid Drug Rebate Statute and applicable regulations, drug manufacturers must report "best prices" that reflect all discounts and rebates for

the sale of the same drug unit, even if the manufacturer provides those discounts to different entities in the chain of distribution.

II. The district court likewise erred in holding that the relator failed to plausibly allege that Forest acted knowingly under the False Claims Act. Relator made specific factual allegations that, if true, would support a reasonable inference that the defendant actually knew that it was submitting inflated "best price" reports that were false under the government's understanding of the term, or that it deliberately ignored or recklessly disregarded red flags to that effect. The district court was incorrect to conclude that the mere existence of regulatory ambiguity precluded those allegations. The court also improperly took a fact question away from the jury by determining at the pleading stage that applicable regulatory guidance was insufficient to warn Forest away from its conduct.

ARGUMENT

I. The District Court Erred In Holding That Ambiguity In The "Best Price" Requirements Prevented Forest's Price Reports From Being False As A Matter Of Law.

The False Claims Act imposes civil liability where a defendant knowingly presents to the government a "false or fraudulent claim" or "a false record or statement material to an obligation" owed to the government. 31 U.S.C. § 3729(a)(1)(A), (B), (G). A false claim or statement can "take many forms," including "claim[s] … provided in violation of contract terms, specification, statute, or

regulation." S. Rep. No. 99-345, at 9 (1986); *see Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 786 (4th Cir. 1999) (claims may be false in a "variety of ways").

Courts have long recognized that a claim or statement can be false when it is made in violation of applicable law. *See, e.g.*, *Harrison*, 176 F.3d at 786; *Glynn v. EDO Corp.*, 710 F.3d 209, 216 (4th Cir. 2013). In such cases, the question whether the statement was "false" under the False Claims Act is a legal determination; courts must "interpret[]" the applicable statute or regulation and "determin[e] whether a defendant's representations are accurate in light of applicable law." *United States v. Bourseau*, 531 F.3d 1159, 1164 (9th Cir. 2008).

A. A Drug Manufacturer's "Best Price" Reports Are False Under The False Claims Act If They Violate Applicable Law.

Here, the relator alleges that a drug manufacturer fraudulently reduced its rebate obligations to Medicaid programs under the Medicaid Drug Rebate Statute by reporting inflated "best prices" that failed to reflect discounts and rebates provided to multiple entities on the same drug units. The question whether relator has adequately alleged falsity is a legal issue that requires interpretation of the "best price" statute and regulations. *See United States ex rel. Rostholder v. Omnicare, Inc.*, 745 F.3d 694, 702 (4th Cir. 2014) (answering the falsity question by interpreting statutes and regulations). In particular, the court must determine whether, as relator alleges, the statute and CMS regulations required Forest to aggregate all discounts and rebates paid to multiple entities on the same drug units. If Forest was legally required to do so, and did not,

then its "best price" reports were false. As this Court has explained, a defendant's compliance with law is an "either/or proposition"—the defendant "either complied with the [law] or it didn't." *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 383-84 & n.14 (4th Cir. 2015).

The district court's decision is inconsistent with these straightforward principles. The court recognized that the question whether Forest made false statements "depends on the interpretation of the Rebate Statute." JA353. But it ultimately declined to answer the threshold legal question relevant to falsity: whether or not Forest submitted "best price" reports in violation of law. Instead, the court concluded that it could dismiss relator's claims for failure to allege falsity without making that critical determination, simply because the court could not "conclude that the Best Price provision unambiguously refers to cumulative rebates from all entities." JA358.

That reasoning is mistaken. "[A defendant's] 'reasonable interpretation' of a regulation" does not "preclude[] falsity." *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999). Even if a regulation is "technical and complex, … [its] meaning is ultimately the subject of judicial interpretation, and it is [defendants'] compliance with these regulations, as interpreted by [the] court, that determines whether [defendant's] practices resulted in the submission of a 'false claim.'" *Id.* Accordingly, "courts decide whether a claim is false or fraudulent by determining whether a defendant's representations are accurate in light of applicable law."

Bourseau, 531 F.3d at 1164. As this Court has held, ambiguity in the requirements has no bearing on this threshold legal determination, although it might be relevant to the separate question whether Forest violated the law knowingly. *See Drakeford*, 792 F.3d at 383-84 (claim was "false" because it "in fact, violated the [law]," and "[t]he subjective inquiry—whether [defendant] knew that its claims were in violation of the [law is] covered under the knowledge element").

The district court's contrary holding is fundamentally inconsistent with the text, context, and purpose of the False Claims Act. The Act nowhere requires that a claim or statement be "unambiguously" false at the time it is made (JA358); the statute simply requires that the claim be "false or fraudulent," or that a record or statement be "false." 31 U.S.C. § 3729(a)(1)(A), (B), (G). As this Court has recognized, the Act's broad language reflects Congress's purpose to "reach all types of fraud, without qualification, that might result in financial loss to the Government," and therefore "[t]he phrase 'false or fraudulent claim' … should be construed broadly." *Harrison*, 176 F.3d at 788 (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)). Moreover, the Supreme Court has explained that the term "false or fraudulent" in the False Claims Act is best interpreted by reference to "common-law fraud." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1999 (2016) (quotation marks omitted). And common-law fraud "include[d] more than just claims containing express falsehoods," *id.*, reaching even "ambiguous statements," so long as the defendant had the requisite scienter, *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus.*

Pension Fund, 575 U.S. 175, 201 (2015) (Scalia, J., concurring); *cf.* W. Page Keeton et al., *Prosser & Keeton on the Law of Torts* § 106, at 736-38 (5th ed. 1984). (The tort of "misrepresentation may be found" even when misleading "statements … are literally true").

In concluding that ambiguity in the "best price" requirements precluded Forest's price reports from being false, the district court adopted the kind of atextual limitation on False Claims Act liability that the Supreme Court recently warned is improper. In *Escobar*, the Supreme Court rejected a limitation on the phrase "false or fraudulent claims" to "misrepresentations about express conditions of payment," holding that "[n]othing in the text of the False Claims Act support[ed] [the] proposed restriction," and that "policy arguments cannot supersede the clear statutory text." *Escobar*, 136 S. C.t at 2001-02 (quotation marks omitted). The Court further made clear that "concerns about fair notice and open-ended liability" are best channeled "through strict enforcement of the Act's materiality and scienter requirements"—not by "adopting a circumscribed view of what it means for a claim to be false or fraudulent." *Id.* at 2002 (quotation marks omitted); *see also Oliver*, 195 F.3d at 464 ("A contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met.").

The district court incorrectly asserted that Forest's potential violation of the "best price" statute and regulations does not count as an "objective falsehood" because "imprecise statements or differences in interpretation growing out of a disputed legal question are not false." JA351, 360 (alteration omitted) (quoting *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376-77 (4th Cir. 2008)). This Court has expressly held that a defendant's compliance with law is "an objective inquiry" because it is an "either/or proposition." *Drakeford*, 792 F.3d at 383-84 & n.14. The district court relied on the decision in *Wilson*, but that case concerned an entirely different question: whether a vague contract provision requiring "adequate … maintenance" could create liability under the False Claims Act based on "mere 'allegations of poor and inefficient management of contractual duties.'" *Wilson*, 525 F.3d at 377. To the extent that *Wilson* contains any statements that reach more broadly, those statements were dictum. *See Drakeford*, 792 F.3d at 383-84 & n.14 (explaining that *Wilson* does not stand for a general proposition that legal questions are not objective).[2]

The district court also conflated the falsity and knowledge elements by relying on out-of-circuit decisions that are best read to turn on the absence of culpable

[2] In any event, as several courts have held, the False Claims Act's text only requires that a claim be "false," not "objective[ly] fals[e]." *See United States v. Care Alts.*, 952 F.3d 89, 97, 100 (3d Cir. 2020) ("objectivity speaks to the element of *scienter*, not *falsity*"); *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018).

knowledge. For example, in *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999), the Seventh Circuit affirmed dismissal of a False Claims Act claim because the relator offered "no reason to believe that the [defendant] was out to cheat the federal government." Likewise, in *United States ex rel. Hixson v. Health Management Systems, Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010), the Eighth Circuit's holding turned on a finding that the defendant "could not have acted with the knowledge that the [False Claims Act] requires before liability can attach." These cases thus focused more on knowledge than falsity. And even if these cases are read otherwise, the district court should have instead followed this Court's holding in *Drakeford* that falsity turns solely on compliance with the law. 792 F.3d at 383-84.

B. Relator Plausibly Alleged That Forest's "Best Price" Reports Were False.

Because the district court fundamentally erred in assessing falsity, this Court could reverse and remand on this basis alone. There is accordingly no need to decide in the first instance whether relator's interpretation of the "best price" statute and regulations is correct. *See, e.g.*, *Lovelace v. Lee*, 472 F.3d 174, 203 (4th Cir. 2006). But if the Court reaches this question, it should hold that relator has plausibly alleged that Forest violated the "best price" requirement by failing to aggregate discounts and rebates offered to multiple entities for the same drug units.

The Medicaid Rebate Statute defines the drug manufacturer's "best price" as "the lowest price available from the manufacturer … to *any* wholesaler, retailer,

nonprofit entity, or governmental entity," which "shall be inclusive of cash discounts, … , volume discounts, and rebates." 42 U.S.C. § 1396r-8(c)(1)(C)(i), (ii)(I) (emphasis added). "Congress' use of the word 'any' suggests an intent to use that term expansively." *Smith v. Berryhill*, 139 S. Ct. 1765, 1774 (2019) (alterations and quotation marks omitted). And an expansive interpretation is particularly appropriate because Congress intended to "give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 101-881, 96. Reading the word "any" to mean "any single" entity would lead to anomalous results that contradict that purpose. It would mean that if a manufacturer contracts with several entities for the sale of the same drug unit, and spreads its discounts among those entities, the "best price" would reflect only one of several discounts, and Medicaid programs would therefore pay a higher amount for the drug than what the manufacturer realized from private sales.

The same conclusion follows from the way in which Congress used the term "best price." The statute speaks of "the manufacturer's best price," and the prices "available from the manufacturer." 42 U.S.C. § 1396r-8(b)(3)(A)(i)(II), (c)(1)(C)(i). Where a manufacturer provided several discounts or rebates to multiple entities in the course of selling the same drug unit, the ordinary meaning of the phrase "manufacturer's best price" would include all of those discounts. In that context, no one would refer to the "manufacturer's best price" as meaning the regular price minus only one of those discounts. *See, e.g.*, *Bond v. United States*, 572 U.S. 844, 861 (2014)

("In settling on a fair reading of a statute, it is not unusual to consider the ordinary meaning of a defined term, particularly when there is dissonance between that ordinary meaning and the reach of the definition"); *Leocal v. Ashcroft*, 543 U.S. 1, 11 (2004) (applying a similar principle).

CMS's guidance and regulations (by which Forest agreed to abide) have been consistent with those statutory features, and required Forest to aggregate discounts and rebates to multiple entities. The CMS Rebate Agreement in place during the relevant time stated that "[t]he best price for a quarter shall be adjusted by the Manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." 56 Fed. Reg. at 7050. A 1994 CMS Program Release stated that "best price" includes "any price adjustment which ultimately affects the price actually realized by the manufacturer." 1994 Program Release at 1. And a 2007 regulation stated that "Best price shall be calculated to include *all* sales and associated rebates, discounts and other price concessions provided by the manufacturer to *any* entity" and "shall be net of cash discounts … and *any other* discounts or price reductions and rebates … which reduce the price available from the manufacturer." 72 Fed. Reg. at 39,242 (emphases added).[3]

[3] Similarly, in CMS's preamble to a 2016 rule, CMS reiterated that "[i]f a manufacturer offers multiple price concessions to two entities for the same drug transaction … all discounts related to that transaction … should be considered in … determining the best price." 81 Fed. Reg. 5170, 5252-53 (Feb. 1, 2016).

The language in these provisions naturally includes discounts and rebates offered to multiple entities in the course of selling the same unit of drug—particularly since the Rebate Agreement states that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." 56 Fed. Reg. at 7053. That result reflects the best reading of the Medicaid Rebate Statute, and at the very least represents a "reasonable interpretation" to which courts should defer. *See Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984). Accordingly, Forest's "best price" reports were required to reflect all discounts and rebates that Forest paid to multiple entities on the same drug unit. Because they did not, they were false.

The district court agreed that this interpretation was plausible, JA354, but declined to adopt it based on several mistaken observations. The court concluded that the definition of "average manufacturer price" clearly required manufacturers to aggregate discounts to multiple entities, but theorized that the definition of "best price" might not. JA355. But if the "average manufacturer price" clearly requires aggregated discounts, then the "best price" must as well, as it would make little sense for the "average" price to be lower than the "best" price. The court also saw inconsistency between CMS's use of the phrase "price actually realized by the manufacturer" and the phrase "price available from the manufacturer." JA357-58 (quotation marks omitted). Yet both of those phrases are consistent in focusing on the *manufacturer*'s point of view.

More fundamentally, even if there were ambiguity, the question is how best to apply the statute and regulations to the context of a complex sale where a manufacturer contracts with several entities for the sale of the same drug unit, and spreads discounts or rebates among all of them. The text, context, and history of the statute and applicable regulations all point to the same conclusion: the "manufacturer's best price" includes all of those discounts.

II. The District Court Erred In Holding That Ambiguity In The "Best Price" Requirement Precluded The Relator From Plausibly Alleging That Forest Knowingly Violated Those Requirements.

The district court likewise erred in assessing relator's allegations that Forest knowingly violated the "best price" requirements. The False Claims Act imposes liability on a person who submits a false claim to the government with "actual knowledge," "deliberate ignorance," or "reckless disregard of the truth." 31 U.S.C. § 3729(a)(1)(A)-(B), (b)(1)(A)(i)-(iii). "[N]o proof of specific intent to defraud" is "require[d]." *Id.* § 3729(b)(1)(B). Knowledge under the False Claims Act is a fact-intensive question that is ordinarily left for the jury. *See, e.g.*, *United States v. Mallory*, 988 F.3d 730, 738 (4th Cir. 2021) (upholding jury's conclusion regarding knowledge).

In cases involving the violation of an ambiguous regulatory requirement, a defendant can still act with knowledge in several ways. For example, a defendant can actually "know that the [government] interpreted the regulations in a certain way." *United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp.*, 276 F.3d 1032, 1053-54 (8th Cir. 2002). A defendant can also recklessly disregard notice

of a contrary interpretation or fail to make reasonable inquiries. *See United States v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013) (defendant recklessly disregarded that the claim was "potentially false"). And a defendant can act with deliberate ignorance by engaging in "ostrich-like" conduct and ignoring red flags that its conduct is illegal. *See United States v. Krizek*, 111 F.3d 934, 942 (D.C. Cir. 1997); *see also* S. Rep. No. 99-345, 4, 7 (noting Congressional intent to reach "ostrich-like" conduct because "those doing business with the Government have an obligation to make a limited inquiry to ensure the claims they submit are accurate."); H.R. Rep. No. 99-660, at 21 (1986) (explaining "that persons who ignore 'red flags' that the information [in a claim] may not be accurate or those persons who deliberately choose to remain ignorant … should be held liable under the Act.").

Numerous courts have thus recognized that a defendant can act with "knowledge" under the False Claims Act even when a regulatory requirement is ambiguous. *United States ex rel. Phalp v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1155 (11th Cir. 2017) ("Although ambiguity may be relevant to the scienter analysis, it does not foreclose a finding of scienter."); *United States v. R&F Props. of Lake Cty., Inc.*, 433 F.3d 1349, 1358 (11th Cir. 2005) (same); *Allina*, 276 F.3d at 1053 (same); *see also Commercial Contractors, Inc. v. United States*, 154 F.3d 1357, 1366 (Fed. Cir. 1998) (explaining that, despite ambiguity in contract language, a defendant may be liable based on "evidence of knowledge that the claim is false or of intent to deceive"). And this Court has

recently rejected the argument that "because [a law] is ambiguous," a defendant "cannot have knowingly violated the False Claims Act." *Mallory*, 988 F.3d at 737.

A. Relator Plausibly Alleged That Forest Acted With Knowledge Under The False Claims Act.

Here, the complaint contains detailed factual allegations that, despite any ambiguity, Forest actually knew it was submitting inflated "best price" reports under the government's understanding of the "best price" requirement, or at least deliberately ignored red flags to that effect.

First, relator alleges that Forest submitted a letter to CMS acknowledging that CMS's regulatory language "suggests that CMS views best price as the net amount realized by the manufacturer on a sale rather than the lowest price to a particular customer," and asking CMS to disavow that interpretation. JA59-60 (emphases and quotation marks omitted). But even though CMS did not make any such disavowal, and instead provided two examples in which "best price" included discounts to multiple entities, Forest continued to submit "best price" reports without aggregating discounts to multiple entities. *Id.*

Second, relator alleges that Forest started a data scrubbing process to identify instances when it paid two rebates to two insurance companies, partly because it knew that rebates to multiple insurance companies could affect its "best price" reports. JA35-36, 69-70. Forest's awareness that rebates to two insurance companies could

make its "best price" reports inaccurate reflects awareness that "best price" at least sometimes includes rebates to multiple entities.

The relator's complaint also identified numerous sources that should have warned Forest away from its interpretation. As discussed, *supra* p. 17, CMS's 1991 Rebate Agreement, 1994 program announcement, and 2007 rule (among others) all were best read to require stacking of discounts offered to multiple entities. *See* JA49-53. And in the 2007 rule's preamble, CMS expressly provided two examples in which "best price" included discounts to multiple entities. *See* JA57-59 (quoting 72 Fed. Reg. at 39,198-99).

At the pleading stage, these detailed facts provide a sufficient basis for the overall allegation that Forest acted with knowledge under the False Claims Act. The complaint identifies numerous facts—including CMS's rulemakings, Forest's own letter to CMS, and Forest's decision to identify rebates paid to multiple insurers—from which a jury could reasonably infer that Forest actually knew that the government interpreted "best price" to include discounts and rebates to multiple entities. *See Allina*, 276 F.3d at 1053 (if a defendant "kn[ew] that the [government] interpreted the regulations in a certain way and that their actions did not satisfy the requirements of the regulation as the [government] interpreted it, any possible ambiguity of the regulations is water under the bridge"). At the very least, those facts would allow a jury to conclude that Forest deliberately ignored or recklessly disregarded red flags showing that its "best price" reports violated CMS's rules. *See*

Mallory, 988 F.3d at 738 (upholding jury verdict, despite alleged ambiguity in the law, because defendants ignored warnings from attorneys).

B. The District Court Erroneously Dismissed Relator's Plausible Allegations That Forest Knowingly Violated The "Best Price" Requirement.

Despite these allegations, the district court held that relator had not plausibly alleged knowledge under the False Claims Act because the "best price" requirement was ambiguous. The court asserted that because "no judicial authority" had clarified the requirement's ambiguity, "the only question is whether Relator plausibly alleges that CMS regulations and guidance warned Forest away from the view it took." JA360-61. And based in part on its conclusion that relator had "not pointed to a single example where CMS *explicitly* state[d] that manufacturers must aggregate discounts to different customers along the supply chain in a given sale," the court determined that relator had failed to plausibly allege knowledge. JA359-61 (emphasis added).

That holding was mistaken. As this Court and others have held, *supra* pp. 19-21, regulatory ambiguity does not preclude a finding of knowledge under the False Claims Act. Relator's plausible allegations that Forest actually knew it was submitting inflated "best prices" under the government's understanding of the term and that Forest, at a minimum, deliberately ignored numerous red flags indicating that its conduct was unlawful satisfy the knowledge element at the pleading stage.

In addition, the district court focused almost exclusively on the "reckless disregard" prong and the subsidiary question whether Forest had been warned away from an objectively reasonable interpretation of the "best price" requirement. JA360-61. As the district court noted, however, the statute identifies three ways to show a defendant acted knowingly. JA351 (citing 31 U.S.C. § 3729(b)). The court's focus on reckless disregard was thus too narrow.

The cases on which the district court relied do not support its truncated analysis of knowledge. *United States ex rel. Complin v. North Carolina Baptist Hospital*, 818 F. App'x 179, 184 (4th Cir. 2020), for example, expressly declined to hold "that a violation of an ambiguous regulation never can give rise to [False Claims Act] liability." The district court also erred in relying on *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 288 (D.C. Cir. 2015). In *Purcell*, the D.C. Circuit determined that a defendant had not knowingly submitted false certifications on loan applications because the defendant had not been warned away from its reasonable interpretation. *Id.* at 288. This Court recently declined to follow *Purcell* in a case which, like this one, involved "assertedly ambiguous statutory language." *Mallory*, 988 F.3d at 737. And in any event, *Purcell* purported to apply the Supreme Court's discussion of common law recklessness in *Safeco Insurance Co. of America v. Burr*, 551 U.S. 47 (2007). *Purcell*, 807 F.3d at 284, 288. Even if *Safeco*'s discussion of common-law recklessness applies to the "reckless disregard" provision of the False Claims Act, the actual knowledge and deliberate ignorance provisions would permit a finding of knowledge even when the

law was ambiguous. *Cf. Safeco*, 551 U.S. at 60 ("action falling within the knowing subcategory does not simultaneously fall within the reckless alternative"). To the extent that *Purcell* collapsed the False Claims Act's distinct knowledge provisions, this Court should not follow it, as that approach would write "actual knowledge" and "deliberate ignorance" out of the statute.[4]

The district court also overstepped its limited role at the pleadings stage by deciding that, although "some of [CMS's regulations and] guidance could be read to support Relator's interpretation, … the guidance was not so clear as to warn Forest away from its interpretation." JA361. The question whether regulatory materials should have warned a defendant away from a mistaken interpretation is a quintessential factual question. *See Purcell*, 807 F.3d at 289 ("the factual question remains whether there was sufficient evidence that [defendant] was warned away from its interpretation."); *see also Mallory*, 988 F.3d at 738 (upholding jury verdict on evidence that defendants had been warned away from their conduct). The court improperly decided that factual question at the pleading stage.

[4] In addition, *Safeco*'s interpretation of the common law recklessness applies only where there is "no indication that Congress had something different in mind." *Safeco*, 551 U.S. at 70. This Court need not address whether *Safeco* applies to the False Claims Act's recklessness provision. As explained, relator has plausibly alleged knowledge and deliberate ignorance. And relator has alleged recklessness even under *Safeco* because it has plausibly alleged that Forest was warned away from its interpretation.

For example, the district court acknowledged that CMS's 2007 rule provided an example of a situation in which a "best price" should include rebates to multiple entities. But the court determined that this example was insufficient to warn Forest of its error because it was "not directly analogous to Forest's situation." JA359. Such weighing of the evidence was inappropriate at the pleading stage, and ignored that such guidance at least put Forest on notice that "best price" sometimes includes discounts or rebates paid to multiple entities. That clear notice was inconsistent with Forest's alleged interpretation of the "best price" requirement as limited to discounts offered to one entity.

Similarly, the court improperly weighed the probative value of Forest's letter to CMS instead of drawing all reasonable inferences in relator's favor. JA359-360. Although the letter acknowledged that CMS's interpretation of "best price" appeared to include discounts to multiple entities, the court asserted that such letters from Forest and other manufacturers are best read as showing "confusion" and "widespread agreement … over how to calculate Best Price." JA359-60. That approach usurped the role of jury. Although a factfinder could potentially draw the same inferences from this letter as the district court, another inference would be equally reasonable: that Forest either knew or deliberately ignored various indications that it was violating CMS's "best price" requirements.

At bottom, the district court erred in multiple respects by deciding the question of knowledge at the pleading stage. Relator's allegations collectively provided "at least

a triable issue on scienter, which the judge should not have kept from the jury." *Malone v. Microdyne Corp.*, 26 F.3d 471, 479 (4th Cir. 1994); *see Mallory*, 988 F.3d at 738 (upholding jury verdict on knowledge).

CONCLUSION

For the foregoing reasons, the judgment of the district court should be reversed.

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

MICHAEL S. RAAB
CHARLES W. SCARBOROUGH

s/ Joshua Dos Santos
JOSHUA DOS SANTOS
Attorneys, Appellate Staff
Civil Division, Room 7243
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, DC 20530
(202) 353-0213
joshua.y.dos.santos@usdoj.gov

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 6,475 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Joshua Dos Santos
Joshua Dos Santos

CERTIFICATE OF SERVICE

I hereby certify that on March 25, 2021, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system.

s/ Joshua Dos Santos
Joshua Dos Santos

ADDENDUM

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31 U.S.C. § 3729

§ 3729. False Claims

(a) Liability for certain acts.--

(1) In general.--Subject to paragraph (2), any person who--

(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);

(D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;

(E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-4101), plus 3 times the amount of damages which the Government sustains because of the act of that person.

(2) Reduced damages.--If the court finds that--

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

(C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation,

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of that person.

(3) Costs of civil actions.--A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Definitions.--For purposes of this section--

(1) the terms "knowing" and "knowingly" --

(A) mean that a person, with respect to information--

(i) has actual knowledge of the information;

(ii) acts in deliberate ignorance of the truth or falsity of the information; or

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

(2) the term "claim"--

(A) means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that--

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--

(I) provides or has provided any portion of the money or property requested or demanded; or

(II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and

(B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal

employment or as an income subsidy with no restrictions on that individual's use of the money or property;

(3) the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment; and

(4) the term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(c) Exemption from disclosure.--Any information furnished pursuant to subsection (a)(2) shall be exempt from disclosure under section 552 of title 5.

(d) Exclusion.--This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

42 U.S.C. § 1396r-8

§ 1396r-8. Payment for covered outpatient drugs

(a) Requirement for rebate agreement

(1) In general

In order for payment to be available under section 1396b(a) of this title or under part B of subchapter XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

* * *

(b)

* * *

(3) Manufacturer provision of price and drug product information

(A) In general

Each manufacturer with an agreement in effect under this section shall report to the Secretary--

(i) not later than 30 days after the last day of each rebate period under the agreement--

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application

approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act);

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)--

(I) the manufacturer's average sales price (as defined in section 1395w-3a(c) of this title) and the total number of units specified under section 1395w-3a(b)(2)(A) of this title;

(II) if required to make payment under section 1395w-3a of this title, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1395w-3a(c)(2)(B) of this title;

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1395u(o)(1) of this title or section 1395rr(b)(14)(B) of this title, and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs;

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug; and

(v) not later than 30 days after the last day of each month of a rebate period under the agreement, such drug product information as the Secretary shall require for each of the manufacturer's covered outpatient drugs.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v) (relating to the weighted average of the most recently reported monthly average manufacturer prices). For purposes of applying clause (iii), for calendar quarters beginning on or after January 1, 2022, a drug or biological described in the flush matter following such clause includes items, services, supplies, and products that are payable under part B of title XVIII as a drug or biological.

* * *

(c) Determination of amount of rebate

(1) Basic rebate for single source drugs and innovator multiple source drugs

(A) In general

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of--

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of--

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,

for the rebate period.

* * *

(C) "Best price" defined

For purposes of this section--

(i) In general

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding--

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of Title 38, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 256b(a)(4)(L) of this title);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1395w-141 of this title; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of subchapter XVIII, by an MA-PD plan under part C of such subchapter with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1395w-132(a)(2) of this title) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such subchapter, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1395w-114a of this title.

(ii) Special rules

The term "best price"--

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) Application of auditing and recordkeeping requirements

With respect to a covered entity described in section 256b(a)(4)(L) of this title, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 256b(a)(5)(C) of this title.

* * *